51. (Previously added) The chimeric polypeptide of Claim 50, wherein said heterologous polypeptide is an epitope tag or an Fc region of an immunoglobulin.

Remarks/Arguments

The foregoing amendments in the claims are of formal nature, and do not add new matter.

Claims 39-51 are pending in this application and are rejected on various grounds. Without acquiescing to the Examiner's position, and solely to expedite prosecution in this application, Applicants have cancelled Claims 39- 43. The rejections to the remaining claims are respectfully traversed.

Claim Rejections – 35 USC §101

Claims 39-51 remain rejected as allegedly not being supported by either a credible, specific and substantial asserted utility, or a well established utility.

In view of cancellation of claims 39-43, the rejections to these claims is rendered moot. Applicants respectfully traverse the rejection to the remaining claims.

The Examiner points out that "the increased copy number of DNA does not provide a readily apparent use for the polypeptide for which there is no information regarding level of expression, activity, or role in cancer."

Applicants submit that the working hypothesis among those skilled in the art is that, if a gene is amplified in cancer, the encoded protein is likely to be expressed at an elevated level, and hence, such a polypeptide would be useful in detecting cancer. However, increased gene copy number may not *necessarily* result in increased protein expression. To explain polypeptide utility for such circumstances, Applicants have enclosed a Declaration by Dr. Avi Ashkenazi, Ph.D., an expert in the field of cancer biology and an inventor of the present application. As Dr. Ashkenazi explains that,

> "even when amplification of a cancer marker gene does not result in significant over-expression of the corresponding gene product, this very absence of gene product over-expression still provides significant information for cancer diagnosis and treatment. Thus, if over-expression of the gene product does not parallel gene amplification in certain tumor types but does so in others, then parallel monitoring of gene amplification and gene product over-expression enables more accurate

tumor classification and hence better determination of suitable therapy. In addition, absence of over-expression is crucial information for the practicing clinician. If a gene is amplified but the corresponding gene product is not over-expressed, the clinician accordingly will decide not to treat a patient with agents that target that gene product".

Thus, Applicants have demonstrated utility for the PRO343 polypeptide as a tumor marker. Accordingly, the present 35 U.S.C. §101 utility rejections should be withdrawn.

Claim Rejections – 35 USC §112, first paragraph

Claims 39-51 remain rejected under 35 USC § 112, first paragraph, for alleged lack of sufficient written description. The Examiner noted that Applicants had not specifically defined any of the proteins in the broad claimed genus nor any structural characteristics commonly possessed by members of the genus, and hence, allegedly, one of skill in the art would not recognize that the Applicant was in possession of the full breadth of the invention claimed.

In view of cancellation of claims 39-43, the rejections to these claims is rendered moot. Applicants respectfully traverse the rejection to the remaining claims.

Claim 44 and its dependents are well defined in the specification at Figure 98 (SEQ ID NO:263). Thus, one skilled in the art at the effective priority date of the present application would be reasonably accepted that the inventors were in the possession of the invention as claimed. Accordingly, the Examiner is respectfully requested to reconsider and withdraw the present rejection.

The present application is believed to be in *prima facie* condition for allowance, and an early action to that effect is respectfully solicited.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C48). Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: November 10, 2003

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